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Members of the public and patients repeatedly indicate their willingness to take part in research, but current UK research governance regulations provide complex rules about gaining consent. Research participation registers that seek consent from participants to be approached about future studies have several potential benefits, including increased research participation across clinical and healthy populations; simplified recruitment to healthcare research; support for people's autonomy in decision-making; and improved efficiency and generalisability of research. These potential benefits have to be balanced against ethical and governance considerations. With appropriate processes in place, seeking prospective consent to be approached about future studies from patients and members of the public could potentially increase public participation in health research without compromising informed consent and other ethical principles.

Introduction

The quality and generalisability of health research findings are dependent on the participation of sufficiently large numbers of volunteer participants who reflect the diversity of the population. Previous research in the United Kingdom (UK) has shown that 69% of the public are keen to participate in healthcare research¹. Despite this, patients and the public in the UK face at least two important barriers to research participation. First, to protect potential health research participants the UK research governance framework prevents researchers from contacting eligible patients directly; instead the initial contact must come from the clinician responsible for their care². Thus clinicians currently act as the gatekeepers for access to research both for researchers and the potential participants themselves. Second, there is currently no system for matching potentially eligible prospectively consented participants to a range of suitable research studies², so NHS and academic researchers often encounter difficulties in recruiting participants³ to non-clinical research. As a consequence, recruitment is often complicated and slow, and some projects fail. Despite the fact that many studies and researchers find it difficult to recruit suitable people and that many people would participate if they knew a suitable study was available, mechanisms to match potentially eligible participants to suitable research studies often do not exist. One approach to facilitate participation by patients and the public is systematically to ascertain their willingness and interest in participating in future healthcare research and pro-actively seek prospective

consent for future re-contact by researchers for studies for which they are eligible⁴. By linking records to basic demographic and medical history details, researchers can identify eligible and willing participants quickly and efficiently⁵. Despite the possible benefits, this proactive seeking of consent for future re-contact is uncommon, with some exceptions^{4,5,6}.

There are several types of research registers that seek consent from patients or members of the public for ongoing contact regarding future research. This consent is usually prospective with regard to future research in which an individual registrant may have a potential interest and for which they may be eligible to participate. The consent contains two aspects: (1) consent to be enrolled onto the register to provide basic socio-demographic and clinical details, or alternatively to have their details linked to health service related databases; and (2) consent to be contacted at a later date about particular research studies for which they may be eligible, and to receive relevant information to enable them to make decisions about participation. The aims of such registers vary depending on the type of research being undertaken or the particular clinical population being studied. Several research registers have been established around particular health problems or medical specialties to facilitate specific research participation, such as a dementia register⁷ and rare diseases register⁸. Only a relatively small number aim to encourage broad-based research participation, that are non-disease specific, public participation or population based registers. Examples include the Scottish Health Research Register (SHARE)⁹ run by NHS Scotland and 'ResearchMatch' in the USA¹⁰. Moving from disease- or hospital-specific registers to a public participation register provides opportunities for a wide range of people and patients to be involved in a range of research studies, with the added value of potential control groups that may be suitable in some situations. However, given the focus away from specific diseases in specific healthcare setting, a major challenge is to obtain sufficient information so that participants can be informed about studies relevant to them. A register may entail registrants volunteering information about their health via questionnaire on entry, but this is a rather static approach that may become difficult to manage. Alternatively, patients and the public give permission in advance for their electronic health records (EHRs) to be used to assess whether they met the eligibility criteria for studies.

Potential benefits of non-disease specific research registers

Research registers are set up to improve healthcare through increasing research participation, and conducting pragmatic studies more efficiently and on a larger scale¹¹. However, the policy context and legislative

framework around research governance are crucial factors in facilitating or inhibiting the development of research participation registers. In the UK, a system of research regulation and governance, the Research Governance Framework, was instituted in 2001 and re-issued in 2005 to restore public confidence in health research following incidents of poor practice. This has resulted in tight controls on recruitment processes and data collection. The framework has been criticised for introducing burdensome administrative processes, long delays and impeding scientific progress through inflexible procedures (for example Dixon-Wood¹²), although recent legislative and policy changes have sought to improve this situation. Furthermore, mechanisms to encourage greater public involvement in the prioritisation and design of studies, using patient experience to improve research, and national campaigns for improving participation in research have been implemented such as the NIHR 'OK to ask' campaign¹³. These mechanisms are aimed at raising awareness of the importance of health research, which in turn is expected to lead to greater willingness to participate in studies. These recent developments create conditions that facilitate the implementation of research participation registers in the UK.

Much research requires the collection and exchange of electronic patient records and clinical data, and depends on the interoperability of data collection systems and standardised storage. A sustainable strategy for such a digital infrastructure across the English NHS is being developed and data linkage will be important for clinical reasons, as well as for research purposes. While the digital infrastructure for data linkage is being set up, research participation registers are capable of storing large amounts of patient generated data. Therefore, security and privacy in collecting, storing and sharing people's data are major factors in ensuring public trust in any research participation register. However, public trust in initiatives to extract, store and share data digitally cannot be taken for granted even when protective infrastructures and legislation are in place. As Carter et al (2015) argue, the social legitimacy of such undertakings has to be secured through engagement and public approval and what they term a 'social licence', based on reciprocity, non-exploitation and service of the public good. Practical implications for access to individual information and recruitment to studies is highly sensitive and operating procedures will need to be carefully developed to ensure public confidence in the system. Any research participation register would need to actively work with public to secure such a social licence. The authors believe that prospective consent employed within a research register model goes some way towards upholding the NHS constitution, provides an informed choice to members of the public about research

involvement and allows researchers access to consented data. Due to the issues associated with Care.Data (Carter et al, 2015), the authors believe that the prospective consent register model will currently not be widely accepted at a UK wide level, but can be suitable integrated at NHS Trust and Clinical Commissioning Group level.

The validity and generalisability of research findings are contingent upon the participation of volunteers drawn from diverse populations in terms of ethnicity, socioeconomic status, geographic location, health literacy and health status. However, many of these groups are underrepresented in health research. The term 'hard to reach' has become shorthand for describing individuals for whom the usual strategies do not work and is increasingly being used in the research literature to construct the problem of non-participation in research by certain groups, implying that the blame for this underrepresentation lies with these groups themselves¹⁴. However, Wendler¹⁵ demonstrated that minority ethnic communities were on the whole no less likely, and possibly more likely than white people, to agree to participate in health studies. The authors identified the reduced likelihood of being invited to participate as the main barriers to participation by minority ethnic groups rather than a lack of willingness or distrustful attitudes. Reliance on one method of recruitment of minority groups to health and clinical studies such as a research participation register is unlikely to succeed and issues such as the use of easily accessible research sites, reimbursement of travel expenses and help with child care and carer responsibilities will be equally important in enabling people to enrol into a study and prevent drop-out (Wendler et al, 2006). There is evidence of novel methods to encourage previously underrepresented groups to join research registers through working with credible and respected opinion leaders, advertisements in particular locations, and the engagement of community champions to spread information (Rogers et al, 2007). The Illinois Women's Health Registry has used various recruiting strategies, including speaking engagements, health fairs and billboards, alongside virtual marketing and social networking (Bristol-Gould et al, 2010). The development of a research participation register may enable greater access to information about health and clinical research studies by providing unbiased access mechanisms, but only if sufficiently large numbers from minority groups are signed up to the register to enable meaningful answers to relevant research questions.

Furthermore, high profile mechanisms to encourage greater patient and public involvement in the prioritisation and design of research studies are being implemented in a range of settings, using a variety of

methods. It has been recognised that a greater level of public trust and confidence is held in research projects where public and patient involvement has been prioritised (<http://www.hra.nhs.uk/documents/2013/08/patient-and-public-workshops-dialogue-report.pdf>). Therefore, the role of Public and Patient Involvement in the design, development and implementation of research registers should be promoted, in order to enhance the perceived utility and user friendly nature of research registers to the general public.

Prospective consent: benefits and drawbacks

The role of prospective consent within a research participation register framework is to allow individual members of the public to have the choice of being actively involved in the process of research consent and participation. Each participant can be given the opportunity to decide on the number and types of research studies in which they want to be involved depending on their current state of health. Such freedom of choice around participation has the potential to allow prospective participants to play a more informed role in research¹⁶. Being offered to take part in suitable potential studies and having the freedom to choose is likely to increase individuals' willingness to participate in research they feel to be worthwhile. For example, Pullman¹⁷ found that people join registers, such as bio-banks, to take up an opportunity to be altruistic. Research investigating the motivation of those people who enrolled into SHARE found that contributing to research for the 'common good' and a sense of altruism was important to patients¹⁸. With suitable safeguards and clear information, joining a research register may promote autonomy in decision-making about participation in research^{19,20}.

The implementation of a research register could encourage commercial and non-commercial research at a time when commercial collaborations are being particularly encouraged²¹. The Scottish Diabetes Research Network saw an increase of 21% in the number of commercial companies and a 28% increase in academic studies using their register between 2010 and 2011, and both academic and non-academic organisations are keen to use prospective consent research registers²². Some people do not wish to participate in some commercial studies¹⁸ but this can be easily arranged within the register.

There are several key issues involved in the establishment and continued development of research registers. These include the need for a broad base of volunteer participants joining research registers and ensuring that

minority groups are included to reflect the diversity of the population. Secure storage of data and robust governance policies are important to ensure participants have confidence in their security and confidentiality and to ensure research is being conducted to the highest ethical standards. A well-structured policy on commercial companies seeking access to participatory research registers is essential to ensure registrants have clear choices about what type of research they engage with. A flexible participant interface has been identified as key to effective communication between potential research participants and researchers, as well as providing an online participant facility to control prospective consent²³. For example, the 'dynamic consent' model is a new approach to online prospective consent and management that seeks to increase engagement from participants regarding the use of their personal data²³. It is in effect an online secure log-in account for each individual involved in a register to allow them to manage and control their own research profile and update consent preferences in real time. Such a flexible interface also mitigates the need for regular and often cumbersome re-consent procedures.

The durability of consent has been highlighted as a potential issue because there could be considerable time lapses between participants providing consent and being re-contacted for future research²⁴. Research conducted during the establishment of the SHARE register found that patients were ambivalent about making open-ended commitments when they agreed to join the register¹⁸, which implies that regular re-consent was not a high priority issue. Some registers advocate re-consenting; for example, 'ResearchMatch' contacts all participants who have not logged in their online account in 12 months to ensure continued interest, and the Illinois Women's Health Registry requests re-consent yearly^{5,6}. Although many registers do not ask for re-consent within repeated time frames directly, many are in regular contact with participants online or through newsletters, which provides the opportunity for participants to be reminded of their role in the register and of options to withdraw if they wish.

There are important ethical issues associated with all types of consent, such as an individual's mental capacity to consent, the information provided to individuals and the voluntary nature of the consent. The aim of prospective consent is to create an environment in which participants can be informed about new studies for which they are eligible, while ensuring that potential participants give consent in the usual way to be entered into specific trials or projects.

Summary

Seeking prospective consent from patients and members of the public, using a register format, could increase participation in health research without compromising informed consent and other ethical principles. Prospective consent is a proactive approach to improving access to health research and could become part of everyday clinical care within hospital and general practice². If fully integrated into the research process, research registers with prospective consent for re-contact could increase participation enhance the reliability and validity of future research. Research registers support the public and patients to move away from passively waiting for an approach about a relevant study towards being able to actively express an interest in participation in health research. They help match interested people to good quality research projects that are likely to suit them. This will speed up research studies and bringing new treatments into routine use. The creation of a more dynamic link between participants and researchers could create a community approach to the improvement of health services through research.

Authors' contributions

VL, SR and GL drafted the manuscript. RM and JD developed the idea behind the Reach West participatory research register and were leads in exploring the practical, ethical and governance issues associated with establishing and implementing Reach West. CR, AW, JB were involved in the development of the participatory research register and exploring the practical, ethical and governance issues associated with establishing and implementing a research participatory register. All authors read and approved the final manuscript.

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